K133320
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510(k) Summary for SICAT Function

FEB 2 5 2014

Content and format as required by section 21 CFR 807.92
(*http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm142651.htm*)

1. Submitter/510(k) Holder

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Primary Contact: Mr. Dr. Manfred Breuer
Secondary Contact: Mr. Frederik Kunze

Date Prepared: October 17th, 2013

2. Device Name and Device Classification

Proprietary Name:	SICAT Function
Common/Usual Name:	Radiological Visualization Software for Diagnosis and Dental Treatment Planning
Classification Name:	System, Image Processing, Radiological
Regulation Description:	Picture archiving and communications system
Product Code:	LLZ
Regulation Number:	21 CFR 892.2050
Classification Class:	Class II Product

3. Predicate Devices

- SICAT Implant (K103723)
- Materialise SimPlant V 12.0 with OMS Module (K033849, K053592, K081402)

4. Device Description

SICAT Function is a pure software device.

SICAT Function is a software application for the visualization and segmentation of imaging information of the oral-maxillofacial region. The imaging data originates from medical scanners such as CT or Cone Beam - CT scanners.

This information can be complemented by the imaging information from optical

impression systems and jaw tracking devices. The additional information about the exact geometry of the tooth surfaces and the mandibular movement can be visualized together with the radiological data.

SICAT Function is also used as a software system to aid qualified dental professionals with the evaluation and planning of dental treatment options.

The dental professionals' treatment planning information may be exported from SICAT Function to be used as input data for the manufacturing of therapeutic devices such as oral appliances.

5. Intended Use

SICAT Function is a software application for the visualization and segmentation of imaging information of the oral-maxillofacial region. The imaging data originates from medical scanners such as CT or CBCT scanners. It is also used as a software system to aid qualified dental professionals with the evaluation of dental treatment options. The dental professionals' planning data may be exported from SICAT Function and used as input data for CAD or Rapid Prototyping Systems.

6. Device Comparison Table

The following table shows a summary of the intended use, technological characteristics, design and function of SICAT Function and the predicate devices.

	SICAT Function Proposed	**SICAT Implant K103723**	**Materialise SimPlant V 12.0 with OMS Module (K033849, K053592, K081402)**
Intended Use			
	SICAT Function is a software application for the visualization and segmentation of imaging information of the oral-maxillofacial region. The imaging data originates from medical scanners such as CT or CBCT scanners. It is also used as a software system to aid qualified dental professionals with the evaluation of dental treatment options. The dental professionals' planning data may be exported from SICAT Function and used as input data for CAD or Rapid Prototyping Systems.	SICAT Implant is a software application for the visualization of imaging information of the oral-maxillofacial region. The imaging data originates from medical scanners such as CT or DVT scanners. SICAT Implant is intended for use as planning and simulation software to aid qualified dental professionals in the placement of dental implants and the planning of surgical treatments. The dental professionals planning data may be exported from SICAT Implant and used as input data for CAD or Rapid Prototyping Systems.	The SimPlant System is intended for use as a software interface and image segmentation system for the transfer of imaging information from a medical scanner such as a CT scanner or a Magnetic Resonance scanner. It is also intended as pre-planning software for dental implant placement and surgical treatment. Materialise Dental's SimPlant Ortho 3D software is indicated for use as a medical front-end software that can be used by medically trained people for the purpose of visualizing gray value images. It is intended for use as a software interface and image

	SICAT Function Proposed	SICAT Implant K103723	Materialise SimPlant V 12.0 with OMS Module (K033849, K053592, K081402)
			segmentation system for the transfer of imaging information from a medical scanner such as a CT scanner or Magnetic Resonance scanner. It is also used as a software system for simulating/evaluating orthodontic treatment i.e. dental bite options.
Technological Characteristics and Function			
Material	pure software device	pure software device	pure software device
Operating system	Windows	Windows	Windows
Programming language	C# and C++	C# and C++	C++
Medical Data I/O			
Volume data import	DICOM	DICOM	DICOM
Optical surface data/ optical impression import	Standard STL format and proprietary SSI container Format.	Standard STL format and proprietary SSI container Format.	Standard STL format and proprietary OrthoPlex format.
Jaw motion tracking data	from JMT devices in proprietary format defined by SICAT.	No	No
Export of data for CAD and rapid proto-typing	Yes	Yes	Yes
Medical Data Viewing			
Data types visualized	3D volume data, optical impressions, jaw motion data	3D volume data, optical impressions	3D volume data, optical impressions
2D Slice Views	axial, coronal, sagittal, dental panorama, dental tangential and cross-sectional slice views	axial, coronal, sagittal, dental panorama, dental tangential and cross-sectional slice views	axial, coronal, sagittal, dental panorama, dental cross-sectional slice view, cephalometric
3D Volume rendering	Yes	Yes	Yes
3D Surface rendering	Yes	Yes	Yes
View manipulating tools	Scroll, Zoom, Pan, Change of orientation, Brightness, Contrast	Scroll, Zoom, Pan, Change of orientation, Brightness, Contrast	Scroll, Zoom, Pan, Change of orientation, Brightness, Contrast
Other Features			
Measurements	Length, Angle	Length, Angle, Grey values	Length, Angle, Grey values
Segmentation (i.e. of mandible)	Yes, using a segmentation wizard.	No	Yes, using a segmentation wizard

	SICAT Function Proposed	SICAT Implant K103723	Materialise SimPlant V 12.0 with OMS Module (K033849, K053592, K081402)
Registration of optical impression data to volume data	Yes	Yes	Yes
Evaluation of occlusion based on optical impression data	Only visually	No	Yes, color coded
Misc. functions			
Simulation of orthodontic procedures, osteotomies and distractions.	No	No	Yes
Cephalo-metric analysis	No	No	Cephalometric view with length and angular measurements and special tools for different cephalometric schools.
Implant planning	No	Yes	Yes
Soft tissue simulation and photo mapping	No	No	Yes

Missing features of SICAT Function compared to the predicate devices are connected to implant planning, i.e. the planning feature itself and the measurement of grey values, and to the planning of orthognatic surgery, i.e. the simulation of orthodontic procedures, osteotomies and distraction, soft tissue simulation and the cephalometric analysis. This does not impact the safety and effectiveness of SICAT Function concerning the visualization and segmentation of imaging information and the evaluation of other dental treatment options.

Additional features of SICAT Function compared to the predicate devices are the import and visualization of jaw motion data. Performance testing has been used to validate the safety and effectiveness of SICAT Function related to the import and visualization of jaw motion data.

The predicate device SICAT Implant does not provide features for the segmentation of imaging information and for jaw motion data. Otherwise the software algorithms used in SICAT Function are identical to the predicate device SICAT Implant. Performance testing has been used to validate the safety and effectiveness of the SICAT Function segmentation features in comparison to the predicate device Simplant.

7. Non-Clinical Performance Testing and Verification and Validation Activities

For SICAT Function, software verification and validation activities were performed, in accordance with the following Guidances and Standards:

- NEMA PS 3.1 - 3.20 (2011), Digital Imaging and Communications in Medicine (DICOM) Set.

- ISO 14971 Second edition 2007-03-01, Medical devices - Application of risk management to medical devices.
- IEC 62304 First edition 2006-05, Medical device software - Software life cycle processes.
- ANSI/AAMI ES60601-1:2005/(R)2012 and C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text) Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD).
- IEC 62366:2007, Medical devices - Application of usability engineering to medical devices
- SMPTE Recommended Practice RP 133-1991: Specifications for Medical Diagnostic Imaging Test Pattern for Television Monitors and Hard-copy Recording Cameras
- HIPAA 45 CFR Part 160 – General Administrative Requirements
- HIPAA 45 CFR Part 164 – Security and Privacy
- Guidance for the Submission of Premarket Notifications for Medical Image Management Devices, Document issued on: July 27, 2000
- Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, Document issued on: May 11, 2005
- Guidance for Industry, FDA Reviewers and Compliance on Off-The-Shelf
- Software Use in Medical Devices, Document issued on: September 9, 1999
- Device Labeling Guidance, March 8, 1991 (G91-1)
- General Principles of Software Validation; Final Guidance for Industry and FDA Staff, Document issued on: January 11, 2002
- Guidance for Industry, Cybersecurity for Networked Medical Devices Containing Off-the-Shelf (OTS) Software, Document issued on: January 14, 2005
- Medical Device Use-Safety: Incorporating Human Factors Engineering into Risk Management: July 18, 2000

Among others the following verification and validation activities were performed:

- Design Validation/Reviews
- Unit Tests
- Code Reviews
- Usability Tests
- Integration Tests
- System Verification Tests
- User Site Tests

Special bench testing has been performed with non-clinical data:

- to verify the correct import, registration and visualization of jaw motion data and
- to verify the safety and effectiveness of image segmentation features.

Test reports for integration testing, system verification testing and bench testing are included with this premarket notification.

A verification and validation activities summary report provided with this premarket notification concludes that SICAT Function passed all verification and validation activities and that safety and effectiveness of the product has been demonstrated in the context of its intended use.

8. Conclusion

Based on the information and supporting documentation provided in the premarket notification, SICAT Function is considered to be substantially equivalent in design, material and function to the predicate devices. It is believed to perform as well as the predicate devices for the visualization and segmentation of imaging information and the evaluation of dental treatment options. Accordingly we respectfully request the Agency to find this traditional 510(k) premarket notification to be Substantially Equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 25, 2014

SICAT GMBH & CO. KG
% OLAF TEICHERT
THIRD PARTY REVIEWER
TUV SUD AMERICA INC.
1775 OLD HWY 8 NW, STE 104
NEW BRIGHTON MN 55112

Re: K133320
Trade/Device Name: Sicat Function
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: January 16, 2014
Received: January 22, 2014

Dear Mr. Teichert:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

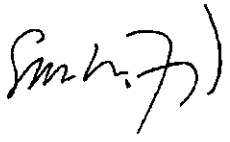
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K133320

Device Name
Sicat Function

Indications for Use *(Describe)*
SICAT Function is a software application for the visualization and segmentation of imaging information of the oral-maxillofacial region. The imaging data originates from medical scanners such as CT or CBCT scanners. It is also used as a software system to aid qualified dental professionals with the evaluation of dental treatment options. The dental professionals' planning data may be exported from SICAT Function and used as input data for CAD or Rapid Prototyping Systems.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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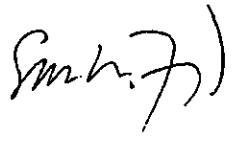
FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*



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